NATURAL RESOURCES DEFENSE COUNCIL

December 18, 2013

By Electronic Case Filing

Hon. Catherine O'Hagan Wolfe, Clerk of Court
United States Court of Appeals for the Second Circuit
Thurgood Marshall United States Courthouse
40 Foley Square
New York, New York 10007

Re: *NRDC et al. v. FDA et al.*, Docket Nos. 12-2106(L), 12-3607(Con)
Response to FDA's Notice of Supplemental Authority

Dear Ms. Wolfe:

Plaintiffs-appellees respectfully submit this letter in response to defendants-appellants' letter of December 13, 2013, which attached FDA's Guidance for Industry #213 and the agency's press release.

In Guidance #213, FDA reaffirms its 1977 findings, never rescinded by the agency, that subtherapeutic uses of penicillin and tetracyclines in animal feed are not shown to be safe for human health: "FDA believes that, in light of the risk that antimicrobial resistance poses to public health, the use of medically important antimicrobial drugs for production purposes in food-producing animals does not represent a judicious use of these drugs." Guidance #213, at 4. Because FDA has never changed its position that such drug uses are not shown to be safe, the agency must conduct the withdrawal proceedings triggered by its 1977 findings. NRDC Br. 17-24.

Guidance #213 also confirms that FDA agrees with the premise of plaintiffs' citizen petitions. The agency admits that "giving antimicrobial drugs to food-producing animals at low levels for long periods of time and in large numbers of animals may contribute to antibiotic resistance." Guidance #213, at 13. But FDA denied the petitions anyway, without considering the required statutory factor: whether the challenged drug uses were shown to be safe. That was arbitrary. *See Massachusetts v. EPA*, 549 U.S. 497, 533-34 (2007).

Rather than comply with the law, FDA offers up an unenforceable guidance document. Guidance #213 warns at the outset that it "does not operate to bind FDA or the public," and the words "voluntary" or "voluntarily" appear forty-three times. Guidance #213, at 3. Neither the Food and Drug Act nor FDA's regulations permit the agency to substitute voluntary measures for binding withdrawal proceedings if the agency finds that an approved drug use is not shown to be safe. NRDC Br. 39-40. Moreover, there is no evidence that Guidance #213 will be effective. Even if some drug

sponsors voluntarily withdraw approved uses of their drugs for growth promotion, the threat to human health will persist, because the same drug uses may continue under the rubric of disease "prevention." Guidance #213, at 4, 7.

Respectfully submitted,

s/ Jennifer A. Sorenson

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cc: Counsel for defendants-appellants (via ECF)